IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re. Application of Thierry-Palmer, et al. Art Unite 1651
USSN 10/617,254 Ex. Lankford
Filed July 11, 2003
TITLE: METHOF FOR IDENTIFYING SALT-SENSITIVE PERSONS

Revised Brief On Appeal

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

This is a revised Brief On Appeal filed in response to the Office Action mailed September 28, 2006.

This is an appeal from the rejection of claims 5-11, all of the claims pending in the current application. The amendment after final was not entered. A clean copy of all of the claims as amended after the first Office Action and after the Advisory Action in accord with a discussion with Examiner Lankford is attached as Appendix 1. No claims have been allowed.

REAL PARTY IN INTEREST:

The real party in interest is Morehouse School of Medicine in Atlanta, Georgia. The inventors are employees of that institution.

RELATED APPEALS AND INTERFERENCES:

There are no related appeals and interferences.

STATUS OF THE CLAIMS:

Claims 1-4 have been cancelled.

Claims 5-11 were previously added and have been amended only to correct dependency with filing of this Brief, since the amendment after final was not entered.

STATUS OF THE AMENDMENTS:

The amendment after final has not been entered. Hence, claims 5-11 as amended after final are not presented. The claims have been amended to correct dependency and it appears, from the discussion with Examiner Lankford, that amendments relating to dependency would be entered. Otherwise, the claims remain as presented after the first action on the merits.

SUMMARY OF THE CLAIMED SUBJECT MATTER:

Claims 5, 9 and 11 claim a kit for measurement of vitamin D binding proteins in urine as a marker for salt sensitivity.

The kit, as claimed in claim 5, comprises radiolabled 25-hydroxyvitamin D_3, unlabeled 25-hydroxyvitamin D_3 and instructions for the measurement of the vitamin D binding proteins. The method is identified at the paragraph bridging pages 2 and 3 and is exemplified at the paragraph bridging pages 6 and 7. The urine samples are incubated to allow binding of the labeled and unlabeled to protein. The binding of protein in the samples containing excess unlabeled 25-hydroxyvitamin D_3 as well as the labeled 25-hydroxyvitamin D_3 and the samples containing only the labeled 25-hydroxyvitamin D_3 were both measured to obtain specific binding. Hence, both the radiolabeled and the unlabeled 25 hydroxyvitamin D_3 are needed for the evaluative process and are, therefore, requirements for a kit for determining the binding protein in the sample.

Referring to claim 9 reciting lack of need for antibodies to 25 hydroxyvitamin D, see lines 5-7 of page 5. See page 4, lines 24 to 26 indicating that such antibodies were required in prior art methods of testing. Hence, the improvement is claimed.

Referring to claim 11, lines 26-31 at page 6 exemplifies use of charcoal in the procedure.

Claims 6, 7, 8 and 10 claim the method of testing for 25-hydroxyvitamin D binding activity. The steps are taught at the paragraph bridging pages 2 and 3 of the application and are exemplified at the paragraph bridging pages 9 and 10. The rational for the developing a method using urine is taught at the paragraph bridging pages 2 and 3. Collection of urine is required in step 1 and is taught at lines 3 and 4 of page 3. Step 2, the addition of a known amount of radiolabled 25-hydroxyvitamin D_3 is taught at page 3, lines 4 and 5. The third step, which is the addition of a known amount of excess unlabeled 25-hydroxyvitamin D_3 to some of the samples, is taught at line page 3, lines 6-11 of page 3. The incubation, as required in step 4, is taught is taught at line 11 of page 3 and is exemplified in the example at lines 25 to 30. Step 5 involving the incubation with buffered charcoal, followed by centrifugation is exemplified at page 6, lines 28 to 35. Step 6, involving the measuring of the radioactivity is exemplified at page 6, line 33 to

page 7, line 1 using the Bio-Safe 11 as the means of counting activity. The method of measuring the activity as indicated in step 7 of claim 6 is found at page 3, lines 12 to 17.

Regarding the claim 7, wherein the urine tested is human urine, this aspect is exemplified in several studies beginning at page 7, line 25, wherein the samples were from African-American men..

The method of claim 8 relating to salt-sensitivity is addressed at page 6, lines 18 to 31.

The method of claim 10 relates to calculation of the binding activity by comparison of the binding activity in samples containing only labeled 25-hydroxy-vitamin D_3 and those containing both labeled and unlabeled 25-hydroxyvitamin D_3 and is exemplified beginning at page 6, line 33 to page 7, line 4. The method is further discussed at page 3, lines 12 to 17.

GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL:

Rejection under 35 U.S.C. 112, second paragraph:

The rejection of claims 6-8 and 11 for failing to identify what is being claimed because they do no identify (1) exactly what is being measured and (2) how it is being measured has been traversed.

Rejection under 35 U.S.C. 103(a) as obvious over DeLucia, et al. (U.S. Patent 4,269,777) and Norman, et al. (U.S. Patent 3,772,150)

The rejection under 35 U.S.C. 103(a) as obvious over DeLucia, et al. ('777) and Norman, et al. ('150) has been traversed.

ARGUMENTS:

Rejection of claims 6-8 and 10 under 35 U.S.C. 112, second paragraph:

While the amendment after final has not been entered, said amendment having been made at the suggestion of the examiner and so amended merely in an attempt to

facilitate prosecution, the claims as now presented are those rejected in the Final Office Action.

The first question is whether the independent claim recites exactly what is being measured. The claim clearly states that what is being measured is the 25-hydroxyvitamin D_3 binding activity in a urine sample, as is clearly stated in the first two lines of claim 6.

The second question under this rejection is whether the claim recites how that which is measured is being measured. It is urged that the art knows how to measure radioactivity as recited in the claims. The steps of preparation of samples along with the recitation of measurement of radioactivity (a widely used method is recited at the last sentence of page 6) would clearly be understood as standard terminology in the art. The steps of preparation of the samples along with the teaching of a means (scintillation) of measuring the radioactivity, a common procedure, would be clearly understood by one of ordinary skill in the art, for which the claims are written. Furthermore, since the specification clearly teaches how to measure the biding activity being measured, the claims could clearly be understood in light of the description. Hence, it is urged that one of ordinary skill in the art would clearly know what is being measured and how it is being measured.

The third question raised is whether the claim clearly recited how that which is measured correlates with salt sensitivity. While the claim was amended after final to recite the basis for the correlation, it is urged that there is no basis for requiring incorporation of the basic teaching underlying the use of the method as taught, namely, the correlation between 25-hydroxyvitamin D binding activity and salt sensitivity, in the claims. No authority for requiring such a recitation in the claim is cited. Hence, it is urged that thought the applicant clearly attempted to conform with what appears to be the examiner's suggestion, applicant believed the claim as presented in the appendix is appropriate and that the basis for performing the measurement as to diagnosis need not be recited in the claims.

Claim 10 identifies how the calculations are made and the last phrase identifies exactly what is the purpose of the claimed method, namely, the determine salt-sensitivity.

Rejection under 35 U>S.C. 103(a) as obvious over DeLucia, et al., (U.S. Patent 4,269,777 and Norman, et al. (U.S. Patent 3,772,150)

Claim 5, reciting a kit containing radiolabeled 25-hydroxyvitamin D_3, unlabeled 25-hydroxyvitamin D_3 and instruction for measurement of vitamin D binding proteins and dependent claims 9 and 11 have been rejected over DeLucia '777 and Norman '150. The rejection has been traversed by the applicant. DeLucia disclosed and claims only methods for making a group of radiolabeled vitamin D compounds and intermediates produced in the methods disclosed therein. There is no teaching therein, nor motivation, to suggest preparation of a kit for any purpose having the components recited in the claims. Thought the examiner has urged it would be obvious to make such a kit, it has been impossible to determine where the examiner finds, in that reference, an motivation or suggestion to make such a product. If such motivation or suggestion is found, enlightenment as to where would be appreciated.

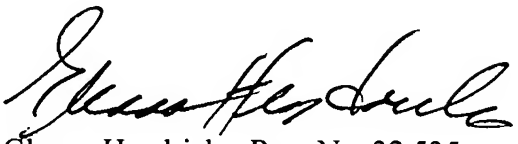
Norman does not provide any additional motivation or teaching that would, with DeLucia, suggest or motivate one to make the kit of the invention. Norman simply teaches a method for making the metabolites of 25-hydroxycholecalciferol using mitochondrial preparations. The question is, does the recitation of one prior art ingredient recited in the claim, said ingredient being, in the prior art, in a culture to make metabolites of the ingredient, suggest a kit containing one of the ingredients as a component for a kit for any purpose? No enlightenment as to how such recitation renders the claimed invention obvious has been provided by the examiner. It is urged by the applicant that the mere recitation of (1) a component of a kit in one prior art reference teaching how to make that component and the recitation of another component (2) recited in the claim as taught in the second prior art reference as an ingredient in a cell culture does not render a kit containing components (1) and (2) obvious for any reason or purpose. Hence, the rejection can not stand.

It is respectfully requested that claims 6, 7, 8 and 10 be deemed to comply with the requirements of U.S.C. 112 second paragraph as to particularly pointing out and distinctly claiming the subject matter the applicant regards as the invention.

It is also requested that claims 5, 9 and 11 be deemed allowably under 35 U.S.C. 103 as unobvious over DeLucia, et al. and Norman, et al. Finally, it is requested that all

claims addressed herein be allowed as amended in the amendment which accompanied the initial Brief on Appeal and as appended hereto.,

Respectfully submitted,



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